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EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,354	BOHM ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-24 and 26-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-24, and 26-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 9 December 2004 does not place the application in condition for allowance.

Status of Objections and Rejections Pending Since the Office Action of 9 August 2004

2. All objections to the specification and claims, and all rejections made under 35 U.S.C. §112 are withdrawn due to Applicant's amendment.

3. All rejections of claims 4 and 25 are withdrawn due to cancellation of the claims.

4. The rejection of claims 1-3, 5-8, 12-24, 26, 30-36, and 38-45 under 35 U.S.C. §103(a) as unpatentable over Simpson et al in view of Howitz et al is maintained.

5. The rejection of claims 9-11 and 27-29 under 35 U.S.C. § 103(a) as unpatentable over Simpson et al in view of Howitz et al and Bjornson et al is maintained.

6. The rejection of claim 37 under 35 U.S.C. § 103(a) as unpatentable over Simpson et al in view of Howitz et al and Sundberg et al is maintained.

7. All other prior rejections are withdrawn.

8. Additional grounds for rejection are presented, which were necessitated by Applicant's amendment.

Prior Claim Rejections - 35 USC § 103

9. The rejections maintained from the prior action are repeated here with modifications necessitated by Applicant's amendment.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1-3, 5-8, 12-24, 26, 30-36, and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al in view of Howitz et al.

Relevant to claim 1, Simpson et al disclose a separation device (Column 1, line 65 - Column 2, line 1) comprising: one or more anode reservoirs (Figure 1, 180; Column 9, lines 25-27)); a plurality of separation channels connected to the anode reservoirs (Column 3, lines 14-28; Column 9, lines 25-27), with each of the separation channels having an interior bounded by a side wall (Figure 4B; Column 4, line 47 - Column 5, line 7); a plurality of fluid inlets to the separation channels (Figure 2, B and C with associated channels to channel 222); and at least one cathode reservoir multiplexed with two or more separation channels. (Figure 1, Reservoir 120)

Relevant to claim 12, Simpson et al disclose a separation device comprising: an array of microfabricated separation channels formed at the surface of a first microfabricated substrate and a corresponding surface of a second substrate bonded to the surface of the first substrate with each channel having an interior bounded by a sidewall, a first end and a second end (Figures 1 and 4B; Column 9, lines 12-17; Column 4, line 47 - Column 5, line 7); an array of fluid inlets to the separation channels (Figures 1 and 2, B and C with associated channels to channel 222); an array of cathode reservoirs connected to the first end of each of the separation channels (Figure 1; Column 9, lines 23-24); and an array of anode reservoirs, wherein at least one anode reservoir is connected to the respective second ends of at least two of the separation channels. (Figure 1; Column 9, lines 25-27)

Relevant to claims 30 and 32, Simpson et al disclose a separation device comprising: a substrate (Column 4, line 47 - Column 5, line 7); a plurality of separation channels formed in the substrate (Column 3, lines 14-28), each channel having an interior bound by a side wall (Figure 4B; Column 4, line 47 - Column 5, line 7); a plurality of fluid inlets to the separation channels (Figure 2, B and C with associated channels to channel 222); an anode reservoir multiplexed to two or more separation channels (Figure 1, Reservoir 180; Column 10, lines 49-57); and a cathode reservoir multiplexed to two or more separation channels (Figure 1, Reservoir 120; Column 10, lines 58-65)

Relevant to claims 2, 16, 17, 22, and 34, Simpson et al disclose an electrode array coupled or coupleable to the reservoirs and fluid inlets within the separation device. (Column 5, line 36 - Column 6, line 37; Column 10, lines 9-10) This array can

be in electrical contact with the device (Figure 4B; Column 10, lines 31-33), or integral with the substrates of the device (Column 10, lines 11-13).

Relevant to claim 3, Simpson et al disclose a separation device with an outer perimeter and a center, with the separation channels connecting the outer perimeter to the center. (Figure 9; Column 9, lines 9-11)

Relevant to claims 8 and 26, Simpson et al disclose their device being a capillary array electrophoresis plate. (Column 1, lines 65-66)

Relevant to claim 14, Simpson et al disclose the first and second substrates being made of glass. (Column 9, lines 66-67)

Relevant to claim 15, Simpson et al disclose the first and second substrates being made of plastic. (Column 10, lines 1-2)

Relevant to claims 18 and 35, Simpson et al disclose the regular spacing of the fluid inlets on one of the substrates to receive solutions from a parallel loading device. (Column 1, lines 13-15; Column 4, line 47 - Column 5, line 7)

Relevant to claims 19 and 24, Simpson et al disclose the first substrate of their device including an array of electrodes aligned with sample reservoirs of the device to make electrical contact with solutions in the sample, waste, anode, and cathode reservoirs. (Column 10, lines 17-23)

Relevant to claim 20, Simpson et al disclose a number of holes, H, approximately equal to 5N/4, where N is the number of samples to be processed. (Column 10, lines 24-27)

Relevant to claim 21, Simpson et al disclose their device being made of a combination of glass and plastic. (Column 10, lines 28-30)

Relevant to claim 23, Simpson et al disclose a plurality of sample fluid inlets in communication with on of the separation channels (e.g. Figure 2, B and C both feed channel 222)

Relevant to claim 36, Simpson et al disclose a parallel loading device comprising a multi-headed pipetter. (Column 11, lines 16-18)

Relevant to claim 38, Simpson et al disclose the disposition of the separation channels in a radial pattern on the separation device. (Figure 9)

Relevant to claim 39, Simpson et al disclose a method of injecting a liquid into their separation device, comprising: connecting a cathode reservoir to the respective first ends of two or more channels (Column 11, lines 29-30); connecting an anode reservoir to the respective second ends of these channels (Column 11, lines 31-32); loading a sample liquid into the sample reservoir; and applying a voltage to inject the sample into the separation channel. (Column 8, lines 32-41; Column 11, lines 33-41)

Relevant to claims 40 and 43, Simpson et al disclose a method of forming a separation device comprising the steps of: forming a plurality of separation channels in the device (Column 11, line 49), each channel being defined by an interior bounded by a side wall (Figure 4B; Column 4, line 47 - Column.5, line 7); forming a plurality of sample reservoirs connected to the channels (Column 11, lines 50-54); connecting an anode reservoir to two or more channels (Column 11, lines 55-56); and connecting a cathode reservoir to two or more channels. (Column 11, lines 66-67)

Relevant to claims 42 and 45, Simpson et al disclose the radial disposition of the channels on the separation device. (Figure 9)

Simpson et al do not explicitly disclose a device comprising: fluid interface ports formed in the side walls of the separation channels to provide access to the interiors of the separation channels, wherein a separation medium disposed in the interior of the separation channel forms a virtual wall at each fluid interface port, and wherein each fluid interface port has a dead volume less than about 1 pL (Claim 1), zero dead volume (Claim 5), or diameters between 25 and 125 μm. (Claims 7, 13, 25, 31, 33) They also do not explicitly disclose a fluid interface port that comprises an array of apertures forming virtual walls. (Claim 6)

Regarding claim 39, Simpson et al do not explicitly disclose forming a droplet from the liquid sample, or directing the droplet to a virtual wall formed by a separation medium in a fluid interface port formed in the sidewall of a separation channel.

Regarding claims 40-45, they also do not explicitly disclose a method comprising forming the plurality of ports in the channel sidewalls by removing portions of the sidewalls to define ports with diameters between 25 and 125 μm.

Relevant to claims 1-38, Howitz et al disclose a device (Figure) comprising: fluid interface ports (capillaries containing menisci 6) formed in the side wall of a fluid channel (9) to provide access to the interior of the fluid channel, wherein a separation medium disposed in the interior of the fluid channel forms a virtual wall at each fluid

interface port (Menisci 6). (Column 3, lines 11-15) Relevant to claim 6, they also disclose a fluid interface port comprising an array of apertures forming virtual walls.

Relevant to claim 39, Howitz et al disclose a method of sample injection comprising: forming a droplet from the liquid sample (Figure, droplet 5; Column 3, lines 31-34), and directing the droplet to a virtual wall formed by a liquid in a fluid interface port formed in the side wall of a flow channel.

Relevant to claims 40-45, they also disclose a method of forming their fluid interface ports, comprising the step of forming fluid interface ports in the channel sidewalls with diameter between 25 and 125 μm. (Column 3, lines 12-15, length and width are 50 μm)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Simpson et al by replacing the sample and waste reservoirs, and their associated side channels with a simple hole or holes through the sidewall to serve as a fluid port, as taught by Howitz et al, because Howitz et al teach the usefulness of their fluid port in introducing fluids to microchannels while preventing outflow of the fluid contained within the channel. (Column 1, lines 53-58) It would also reduce the number of holes required in the device by eliminating the need for injection crosses, this reduction in the number of holes having been taught by Simpson et al to be desirable. (Column 3, lines 50-65)

Further addressing claims 1 and 5, given the definition of dead volume presented in the instant specification (roughly, the volume of liquid held in the port and not flowing

with the fluid within the channel), the dead volume associated with ports such as those of Howitz et al will be variable, as a function of the affinities of the fluids for the surface of the port, among other factors. (Column 3, lines 25-31) As such, the dead volume will be zero or near zero (i.e. less than 1 picoliter) for a clean hydrophobic port surface in a device using aqueous fluids. Such hydrophobicity is an innate property of many polymers known to be useful in manufacturing microfluidic devices (e.g. fluoropolymers) or it could be achieved by using known surface treatments for glass (hexamethyldisilazane, used by Simpson - Column 4, lines 53-56) and silicon (Hydrofluoric acid), and would constitute an obvious modification of the device, because such a surface would minimize loss of the injected sample. (i.e. if an aqueous sample hit a hydrophobic surface in a port configured in the way shown in the Figure of Howitz et al, substantially the entire droplet would immediately fall into contact with the fluid in channel 9, as the contact angle and reduced frictional force would not be sufficient to retain the droplet on this surface)

Further addressing claim 20, by replacing each sample reservoir with a fluid interface port, and eliminating waste reservoirs, the number of holes in this combination device would be reduced to N+A+C, where N is the number of samples to be analyzed, A is the number of anode reservoirs, and C is the number of cathode reservoirs. This sum approaches N as the degree of multiplexing of electrode reservoirs to plural channels increases, and thus is approximately equal to N with a geometry such as that shown in Figure 8 of Simpson et al.

Regarding claim 39, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Simpson et al by altering the injection step by: forming a droplet of the sample and directing it to the virtual wall formed at a fluid interface port by a liquid in the separation channel (in the combination device of Simpson et al and Howitz et al described above), as taught by Howitz et al, because it would reduce waste of the sample liquid.

Regarding claims 40-45, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Simpson et al by replacing the step of forming sample reservoirs and associated side channels with the formation of a simple hole or holes (50 μm length and width) through the sidewall to serve as a fluid port, as taught by Howitz et al, because Howitz et al teach the usefulness of their fluid port in introducing fluids to microchannels while preventing outflow of the fluid contained within the channel. It would also reduce the number of holes required in the device by eliminating the need for injection crosses, this reduction in the number of holes having been taught by Simpson et al to be desirable. (Column 3, lines 50-65)

12. Claims 9-11 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al and Howitz et al as applied to claims 1 and 12 above, and further in view of Bjornson et al.

Simpson et al and Howitz et al disclose combinations as described above in addressing claims 1 and 12.

Neither Simpson et al nor Howitz et al disclose their devices being used for electrochromatography (Claims 9 and 27), pressure-driven chromatography (Claims 10 and 28), or isoelectric focusing (Claims 11 and 29).

Bjornson et al disclose electrophoretic devices used for isoelectric focusing and capillary chromatography. (Column 12, lines 53-59) They also disclose fluid flow in their devices by electroosmosis (Column 11, lines 55-60), which suggests electrochromatography. (i.e. chromatography in which the motion of the mobile phase is caused by an electric field)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Simpson et al and Howitz et al by providing the separation capillaries with a chromatographic medium, immobilized pH gradient, or ampholytes and using the device for electrochromatography or isoelectric focusing, as taught by Bjornson et al, because it would provide useful analytical data about the analytes. It would be well within the abilities of one having ordinary skill in the art to use the channel structure shown by Simpson et al with any known prior art capillary electrophoretic technique, such as those claimed here.

Additionally, electroosmotic force corresponds to a type of pressure driving a fluid through a capillary, and as such, is considered a form of pressure-driven chromatography.

13. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al and Howitz et al as applied to claim 36 above, and further in view of Sundberg et al.

Simpson et al and Howitz et al disclose a combination as described above in addressing claim 36. Simpson et al and Arnold et al also disclose a combination as described above in addressing claim 36.

None among Simpson et al, Howitz et al, and Arnold et al disclose a parallel loading device comprising a pin for carrying and introducing the droplet of a liquid sample to the fluid interface port by contacting the virtual wall.

Sundberg et al disclose a parallel loading device (Figure 2) comprising a pin (38) for carrying and introducing the droplet of a liquid sample (36) to the ports (34) of a microfluidic system.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of either Simpson et al and Howitz et al or Simpson et al and Arnold et al by providing a parallel loading device comprising pins for carrying liquid samples to the fluid interface port, as taught by Sundberg et al, because it would simplify delivery of small droplets. It would be well within the abilities of one having ordinary skill in the art to choose any known means of delivering fluid droplets to a selected spot in a microfluidic device (i.e. the port), such as that taught by Sundberg et al. A technique that delivers a plurality of droplets simultaneously, such as that of Sundberg et al, would be particularly obvious to choose, because it would aid in increasing throughput, decreasing labor, etc.

New Claim Objections

14. Claims 46-48 are objected to because of the following informalities:

a. In claim 46 at line 3 and claim 48 at line 3, there is no antecedent basis for "said separation channels", as only one separation channel was recited earlier in the claim.

b. In claim 47 at line 7, it is unclear how a single cathode reservoir can be "multiplexed" with a single channel, since "multiplex" implies the joining or juxtaposition of plural like elements.

Appropriate correction is required.

New Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosed systems (e.g. Figures 3 and 6-9; Page 12, lines 28-32) require anode and cathode ports in addition to the sample ports, which necessarily requires more holes in the device than the number of samples to be simultaneously processed.

New Claim Rejections - 35 USC § 103

17. Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al in view of Howitz et al.

Each of these claims fully encompasses claim 1 in that they only recite limitations that are present in claim 1, while removing various other limitations. The prior art as applied to claim 1 above therefore also renders these claims obvious, given their open language (i.e. "comprising").

Response to Arguments

18. Examiner notes that Applicant refers to claims 1-48 as pending in the application (For instance, Remarks section; Page 10, 1st paragraph and Page 15, Final sentence), although the Amendments to the Claims section lists claims 4 and 25 as cancelled, and other points within the Remarks section refer to claims 4 and 25 as cancelled. (e.g. Page 10, 2nd paragraph and Page 11, 2nd paragraph) Examiner respectfully requests clarification.

19. Applicant's arguments filed 9 December 2004 have been fully considered but they are not persuasive.

Regarding the modification of the system of Simpson et al, Applicant argues that Simpson does not teach or suggest any alternative means of sample introduction, and in fact teach away from such modification, since the reservoirs are required. (Page 12,

2nd full paragraph) Examiner acknowledges that there is no disclosure of alternate sample introduction means in Simpson et al, but teaching one way of performing a necessary function does not constitute teaching away from any modification.

Regarding the teachings of Howitz et al, Applicant asserts that the fluid microdiode they teach does not have a dead volume of less than one picoliter and that the menisci formed by the fluid at the ports of this device do not comprise "virtual walls". (Amendment, Page 13, 2nd full paragraph - the paragraph bridging Pages 13 and 14)

As was presented in the prior office action, the Examiner considers the dead volume of this fluid microdiode to be variable, as is suggested by Howitz et al. (Column 3, lines 25-31) The dead volume of the port will depend on the affinity of the surface for the liquid in channel 9, pressure differences across the ports, etc. It is reasonable to expect that if the fluid within channel 9 does not wet the surfaces of the ports (i.e. is prevented from entering the port due to surface tension or energy considerations), the dead volume will be less than one picoliter or even approximately zero.

In the case that the liquid does not penetrate the capillaries, the Examiner further considers that the behavior of this meniscus as a "virtual wall" would naturally occur, as there would be no impediment to the liquid on the surface of the meniscus flowing with any net fluid flow in channels 7 and 9. In other words, there would be no apparent difference between the menisci of Howitz and the "virtual walls" of the instant application.

In response to applicant's argument that there is no suggestion to combine the references (Amendment Page 14, 2nd full paragraph), the examiner recognizes that

obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Howitz et al teach the usefulness of their fluid port in introducing fluids to microchannels while preventing outflow of the fluid contained within the channel, and ensuring the injection of a fluid into the channel. (Column 1, lines 53-58) Fluid introduction into a microchannel is needed in the device and method of Simpson et al, and modification to incorporate a different means of fluid introduction with desirable properties would be obvious. This combination would also reduce the number of holes required in the device by eliminating the need for injection crosses, with such reduction in the number of holes having been taught by Simpson et al to be desirable (Column 3, lines 50-65), thus providing another motivation for combination.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (Page 14, 3rd full paragraph), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
February 9, 2005

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